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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,558	10/20/2000	Elfi Biedermann	25846-0003	7777

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/693,558	BIEDERMANN ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-56* is/are pending in the application.

4a) Of the above claim(s) *37-54 and 56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-36, 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Response filed August 17, 2005 to the Restriction Requirement mailed May 25, 2005 is acknowledged. A Restriction Requirement previously set forth was withdrawn. Applicants elect Group II, drawn to methods for reducing side effects or neutralizing side effects of a cancerostatic or immunosuppressive agent comprising administering a compound having vitamin PP activity of formula IV. Further, Applicants were requested to elect single disclosed species of a vitamin PP compound, and where appropriate, a cancerostatic or immunosuppressive agent, as such election would relate to the Group elected in response to the Restriction Requirement. It was clearly noted that nicotinamide had previously been elected. In the response filed August 17, 2005, Applicants failed to re-affirm the election of species, as requested, and instead of reciting species, responded with the generic response, "a compound that is nicotinic acid as a compound of Formula III", and "a compound that is nicotinamide of formula V". Because two species have not been elected, as proposed, this election is nonresponsive. However, in the interests of advancing prosecution, an Action follows based on the election of species made by Applicants on February 6, 2003.

Accordingly, claims 37-54 and 56 are presently withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. The subject matter now under consideration are those methods of reducing side effects or neutralizing side effects of a cancerostatic or immunosuppressive agent wherein nicotinamide or nicotinic acid is the compound administered, claims 32-36 and 55.

Applicants are requested to send a complete list of co-pending and related applications, regardless of the stage of prosecution, for any of the ten named inventors that relate to the present method of use.

A Response filed March 3, 2005 to the Office Action mailed July 6, 2004 is acknowledged.

The abstract of the disclosure is objected to because it is not directed to the subject matter presently under consideration. Correction is required. See MPEP § 608.01(b).

The present claims were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and use the invention.

This rejection is withdrawn as it applies to the administration of nicotinamide or nicotinic acid. The specification provides support on pages 110-115 for neutralization of the growth-inhibiting effect of an anti-tumor substance K22.097, by administration of nicotinic acid or nicotinamide in human leukemia cells, in normal leukocytes, in primary intestine cells and in NMRI mice.

Claims 32-36 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitation "or a prodrug thereof" in claims 32, 33, 35, 36 and 55 lacks clarity with respect to the compounds Applicants contemplate as "prodrugs". The specification provides no guidance as to those compounds that have vitamin PP activity and may be

administered in methods for reducing side effects of a cancerostatic or immunosuppressive agents. The metes and bounds of the term "prodrug" cannot be precisely determined in this case.

Applicants' arguments with respect to claims 32-38 that remained rejected in the last Office Action under 35 U.S.C. 102(a) as being anticipated by Budihardjo et al., Clinical Cancer Research, have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-36 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Nurmukhembetov et al., Kardiologia, (abstract)

Nurmukhembetov teaches the administration of the compound having PP vitamin activity, niacinamide, to reduce side effects relating to cardiac contractility as a result of an injection of the cancerostatic agent adriblastin.

Claims 32-36 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Giri et al., Advances in experimental medicine and biology, (abstract)

Giri teaches the administration of the compound having PP vitamin activity, niacin, to reduce the chemically-induced side effect interstitial pulmonary fibrosis that results from administration of the cancerostatic agent bleomycin.

Claims 32-36 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens et al., British Journal of Dermatology, (abstract)

Stevens teaches the administration of the compound having PP vitamin activity, nicotinic acid, to neutralize a dermatologic side effect, a rash, that was exacerbated by administration of the cancerostatic agent 5-fluorouracil. Pellagra is presented as a chemically-induced side effect secondary to 5-fluorouracil.

The rejection of record in the last Office Action under 25 U.S.C. 102(b) as being anticipated by Artemov is withdrawn as it does not apply to the current claims under consideration.

No claim is allowed.

Vinogradov et al., Voprosy pitaniia, is cited to show further the state of the art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 30, 2005

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER